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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,484	09/22/2003	Venkatram P. Shastri	T1118/20071	2930

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EXAMINER

VANIK, DAVID L

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/668,484

Applicant(s)

SHASTRI ET AL.

Examiner

David L. Vanik

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 8-13, 21, 23, 24, 27-30 and 32-52 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 14-20, 22, 25, 26 and 31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/24/2004</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Response to Election/Restriction filed on 11/7/2005.

Election/Restrictions

Applicant's election with traverse of Claims 1-31 in the reply filed on 11/7/2005 is acknowledged. The traversal is on the ground(s) that Groups I and III should be examined together and do not pose a burden on the examiner because they are members of the same class and subclass. This is not found persuasive because the inventions related to Groups I and III involve materially different scopes. Specifically, Invention I is drawn to a device comprising a functional layer associated with a surface, wherein said functional layer comprises functionalized particles whereas Invention III is drawn to a device comprising a functional layer associated with a surface, wherein said functional layer comprises **monomeric** functionalized particles. Because Invention III, unlike Invention I, involves the presence of monomeric functionalized particles, the inventions are patentably distinct. It should be noted that the following species have been elected for prosecution: metals (11a), oxides (12b) and chemical functional group (13a). Claims 8-13, 21, 23-24, 27-30, 32-52 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species and invention, there being no allowable generic or linking claim. As such, claims 1-7, 14-20, 22, 25-26, and 31 are pending in the instant application. Applicant timely traversed the restriction

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(election) requirement in the reply filed on 11/7/05. The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-7, 14-20, 22, 25-26, and 31 are rejected under 35 U.S.C. 102(e) as being rejected by US 2004/0115416 ('416).

'416 disclose compositions comprising a ceramic layer associated with a surface (abstract). Specifically, the ceramic layer comprises particles disposed onto a substrate surface, such as stainless steel or metal (paragraphs 0001, 0003, 0029-0033 and Clams 1-12). Like the instant application, the particles can have average diameters between 5 nm and 1 micron and can be composed of an oxide, such as silicone dioxide (paragraph 0012). The oxide particles associated with the substrate can be functionalized, comprising alkylsilanes or carboxyamides for example (paragraphs 0001, 0015, 0019, 0023). Like the instant application, the composition advanced by

'416 can be used as a medical device and, as such, is expected to be biocompatible for application to a multicellular organism (claim 11). It should be noted that the use of the composition as an implantable drug delivery device is considered to be a future intended use of the composition and, as such, is given no patentable. Moreover, the use of the functional group to modify the adhesion, friction, wettability, texture, or roughness of a composition can also be considered a future intended use of the composition.

It is the examiner's position that, inherently, the particles in the composition advanced by '416 have a ratio of a major axis to a minor axis of about 1.0 to 1.2 and a polydispersibility of less than 0.01. Since the essential elements of the '416 composition are identical to the instant compositions (that is, an oxide-based functionalized particle associated with a substrate), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '416 anticipates the compositions enumerated in the instant claim set.

Claims 1-6, 14-20, 22, 25, and 31 are rejected under 35 U.S.C. 102(b) as being rejected by US 5,814,550 ('550).

'550 disclose colloidal silica films capable of being associated with substrates (abstract). According to '550, the substrates may be metal and the films comprise silica particles (column 4, line 5 and column 4, lines 26-56). The silica particles can have an

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average diameter of approximately 12 nanometers and may be surface modified or functionalized (column 4, lines 19-56, column 5, lines 20-45, and column 16, lines 7-28). It is the examiner's position that the composition advanced by '550 is biocompatible with a multicellular organism. It should be noted that the use of the composition as an implantable drug delivery device is considered to be a future intended use of the composition and, as such, is given no patentable. Moreover, the use of the functional group to modify the adhesion, friction, wettability, texture, or roughness of a composition can also be considered a future intended use of the composition.

It is the examiner's position that, inherently, the particles in the composition advanced by '550 have a ratio of a major axis to a minor axis of about 1.0 to 1.2 and a polydispersibility of less than 0.01. Since the essential elements of the '550 composition are identical to the instant compositions (that is, an oxide-based functionalized particle associated with a substrate), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '550 anticipates the compositions enumerated in the instant claim set.

Claims 1-5, 14-19, 25-26, and 31 are rejected under 35 U.S.C. 102(b) as being rejected by US 6,086,863 ('863).

'863 disclose therapeutic compositions comprising microspheres used for accelerating wound healing (abstract). According to '863, the microspheres may have a

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mean diameter in the range of 0.01 to about 200 microns and may be chemically functionalized with carboxy and amino groups (column 4, lines 32-50; column 17, lines 15-24; and Table 1). The microspheres can be applied directly to the wound or can be delivered via a bandage (Example 5: column 20, lines 30-41). Specifically, a bandage (comprising a surface) may be soaked with the microspheres and applied to a wound (Example 5: column 20, lines 30-41). After the bandage is soaked with the microspheres, it is the examiner's position that a surface (bandage) is associated with a functional layer (microspheres). It should be noted that the use of the composition as an implantable drug delivery device is considered to be a future intended use of the composition and, as such, is given no patentable. Moreover, the use of the functional group to modify the adhesion, friction, wettability, texture, or roughness of a composition can also be considered a future intended use of the composition.

It is the examiner's position that, inherently, the particles in the composition advanced by '863 have a ratio of a major axis to a minor axis of about 1.0 to 1.2 and a polydispersibility of less than 0.01. Since the essential elements of the '863 composition are identical to the instant compositions (that is, a functionalized particle associated with a substrate), the composition would inherently have the same physiochemical properties as the compositions set forth in the instant application. As such, it is the examiner's position that the composition advanced by '863 anticipates the compositions enumerated in the instant claim set.


Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David L. Vanik whose telephone number is (571) 272-3104. The examiner can normally be reached on Monday-Friday 8:30 AM - 5:00 PM.

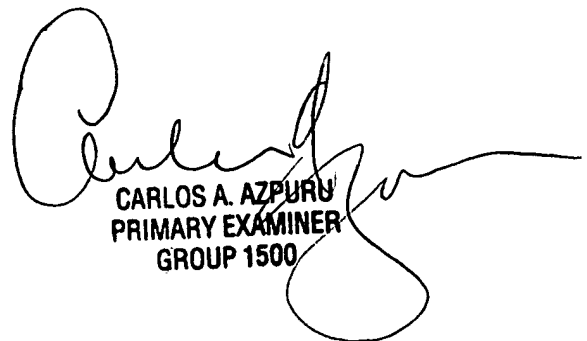
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Vanik, Ph.D.
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1/21/2006



CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500